UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

PUBLIC PENSION FUND GROUP, et al.	)	
	)	**CASE NO. 4:08-CV-1859 (CEJ)**
Plaintiffs,	)	
v.	)	**JURY TRIAL DEMANDED**
KV PHARMACEUTICAL COMPANY, et al.	)	**CLASS ACTION**
Defendants.	)	

LEAD PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION PURSUANT TO RULE 59(e) AND RULE 60(b)(2) FOR RELIEF FROM THE ORDER OF DISMISSAL TO AMEND THE PLEADINGS PURSUANT TO RULE 15

Court-appointed Lead Plaintiffs, the Norfolk County Retirement System and the State-Boston Retirement System (collectively, "Lead Plaintiffs") respectfully submit this memorandum of law in support of their motion pursuant to Federal Rules of Civil Procedure 59(e) and 60(b)(2) seeking relief from the Court's Memorandum and Order (Dkt. No. 117) and Order of Dismissal (Dkt. No. 118), entered on February 22, 2010. The specific relief requested consists of leave to amend the pleadings pursuant to Rule 15.

As set forth in more detail below, Lead Plaintiffs' motion is based on Defendant KV Pharmaceutical Company's ("KV" or the "Company") revelation on February 25, 2010 (after the dismissal) that KV's subsidiary, ETHEX, pled guilty to two criminal felony counts that arise out of the same conduct that forms the basis of certain claims here.

Plaintiffs attach a copy of the proposed amended pleading (the Second Amended Consolidated Complaint, "SAC") as Exhibit A hereto.[1]

I. FACTS

On February 25, 2010, three days after the Court entered the Order of Dismissal, KV issued a press release announcing that it had reached a settlement with the U.S. Department of Justice resolving certain criminal charges. (SAC ¶ 104). More specifically, pursuant to the settlement, ETHEX pled guilty to two felony counts as a result of failing to report the discovery of **oversized tablets** that did not meet product specifications. ETHEX also agreed to pay over $27 million in aggregate fines, restitution and administrative forfeitures. (*Id.*)

On March 2, 2010, the United States Attorney for the Eastern District of Missouri filed a criminal Information (the "Information") in *United States of America v. Ethex Corp.*, No. 4:10-

[1] Lead Plaintiffs filed a Notice of Appeal of the Order of Dismissal concurrently herewith out of an abundance of caution. If the Court were to grant this motion and allow Lead Plaintiffs leave to replead, Lead Plaintiffs will withdraw the Notice of Appeal.

CR-00117-ERW. (SAC ¶ 105). The Information stated that ETHEX acted with scienter, specifically, "with the intent to defraud and mislead." (Information ¶¶ 19, 21, attached as Exhibit 4 to the SAC). The Information further stated that an unnamed senior executive of the Company purposefully failed to report serious manufacturing problems to United States Food and Drug Administration ("FDA"), and instructed KV employees to engage in a cover-up. Specifically, this Corporate Executive (i) "instructed multiple KV employees to minimize written communications about KV's oversized tablet manufacturing problems, and limit distribution and discussion of any documents discussing these problems given the 'business risk' created by written material;" (ii) "was worried that communicating problems to FDA could lead to FDA insisting on additional recalls, and also wanted to limit the Audit Committee's investigation;" and (iii) "was concerned about the number of complaints that KV had received after two morphine sulfate recalls, and thought it was better to leave the drug products 'on the market.'" (Information ¶ 10). This Corporate Executive then instructed KV employees "to do nothing," and refused to allow notification to FDA or further drug recalls. (Information ¶ 9).

According to the Information, "it was unlawful for any person or corporation, with the intent to defraud and mislead, to fail to . . . make any report required under 21 U.S.C. § 355(k), including [field alerts] records required under 21 C.F.R… § 314.81." (Information ¶ 17). As a result, ETHEX pled guilty to two counts of failing to notify FDA through "field alerts" of oversized tablets of **Propafenone and Dextroamphetamine**. (Information ¶¶ 19, 21).

This conduct falls squarely within the allegations made by Plaintiffs in their Consolidated Amended Complaint (Dkt. No. 66) (the "Amended Complaint"). The Amended Complaint alleged that, "FDA requires the submission of a 'FDA Field Alert' within three business days of such a finding. KV did not notify the FDA despite the fact that it knew that at least 10 more

products had oversized tablets, including Isosorbide, **Propafenone, Dextroamphetamine**, Sulfate Tabs and Piaratase." (Amended Complaint ¶ 54(a); emphasis supplied).

II. LEGAL ARGUMENT

"Rule 59(e) and Rule 60(b)(2) are analyzed identically." *United States v. Metro. St. Louis Sewer Dist.*, 440 F.3d 930, 933 n.3 (8th Cir. 2006).

Rule 59(e) states in relevant part, "[a] motion to alter or amend a judgment must be filed no later than 28 days after entry of the judgment." Plaintiffs have filed the instant motion within the prescribed period. "Rule 59(e) motions serve the limited function of correcting "'manifest errors of law or fact or to present newly discovered evidence.'" *Metropolitan*, 440 F.3d at 933 (citations omitted). Similarly, Rule 60(b)(2) states in relevant part, "[o]n motion and just terms, the court may relieve a party or its legal representative from a final judgment, order, or proceeding for the following reasons: . . . (2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b)."

To prevail on a Rule 59(e) or Rule 60(b)(2) motion, the movant must show that: (1) the evidence was discovered after the court's order, (2) the movant exercised diligence to obtain the evidence before entry of the order, (3) the evidence is not merely cumulative or impeaching, (4) the evidence is material, and (5) the evidence would **"probably"** have produced a different result. *Mansfield v. Stanley*, No. 07-1408, 2009 WL 1588660, at *4 (E.D. Mo. June 5, 2009) (citing elements of Rule 60(b)(2); emphasis supplied). *See also Metropolitan*, 440 F.3d at 933 (citing same elements for Rule 59(e)).

Plaintiffs satisfy these elements. With respect to the first two, the Information and guilty pleas were announced after the February 22, 2010 Order of Dismissal, so it was impossible for Plaintiffs to have obtained the evidence beforehand. With respect to elements three and four, the

new evidence is material and not cumulative. The Information conclusively established for the first time that KV's failure to file field alerts (i) constituted criminal **violations**, (ii) with "intent to defraud and mislead." And finally, the evidence would "probably" have produced a different result. The Information establishes violations of federal statutes. It further establishes that a KV Corporate Executive knew that oversized tablets had been distributed into the marketplace and purposefully concealed this from FDA and the public because of concerns of additional recalls and further "business risk" to KV. It is "probable," in light of this revelation, that the Amended Complaint would have been sustained, at least in part.

III. REQUESTED RELIEF

Lead Plaintiffs respectfully request that the Court vacate its order of dismissal and grant leave to file an amended pleading pursuant to Rule 15. *Baumann v. Goodman L.P.*, 2009 WL 4042123, *1 (E.D. Mo. Nov. 19, 2009) (court should freely give leave to amend when justice so requires). The Court should grant leave to amend for the same reasons that relief from the Order of Dismissal and Memorandum and Order is warranted pursuant to Rules 59(e) and 60(b)(2).

In addition to adding the new allegations discussed above to the amended pleading, Lead Plaintiffs have added two expert reports that cure the deficiencies set forth in the Court's Memorandum and Order.

The Memorandum and Order was largely based on the Court's finding that "the Form 483s issued to KV only contained observations – not 'a list of cGMP violations' as alleged by lead plaintiffs." (Order of Dismissal at 16). Lead Plaintiffs have now added an expert report by Benjamin L. England opining that the use of the terms "violations," "deficiencies" and

"observations" is interchangeable. Mr. England bases his opinion, in part, on the FDA Complaint for Permanent Injunction filed on March 2, 2009.[2]

Lead Plaintiffs have also added the expert report of Candace L. Preston, who opines that the existence of the Forms 483 was not in the public domain during the period of the alleged fraud. This addresses the Court's dismissal of the alleged omissions on the basis that the "securities laws require disclosure of information that is not otherwise in the public domain." (Order of Dismissal at 22).

IV. CONCLUSION

For the foregoing reasons, Lead Plaintiffs respectfully request that the Court sustain their motion, vacate the Order of Dismissal and grant them leave to file an amended pleading.

Dated: March 18, 2010

Respectfully submitted,

/s/ Javier Bleichmar

Christopher J. Keller
Javier Bleichmar
LABATON SUCHAROW LLP
140 Broadway
New York, New York 10005
Telephone: 212-907-0700
Facsimile: 212-818-0477
Lead Counsel
On Behalf Of Lead Plaintiffs

[2] *United States of America v. KV Pharmaceutical Company, et al.*, Eastern District of Missouri, No. 09-334 (RWS).

Ted R. Osburn, #50689
Jason G. Crowell, #85931
Michael D. Murphy, # 12684
OSBURN, HINE, YATES
& MURPHY, L.L.C.
3071 Lexington Ave.
Cape Girardeau, Missouri 63701
Telephone: 573-651-9000
Facsimile: 573-651-9090
Liaison Counsel
On Behalf of Lead Plaintiffs